4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1398]

Mitigation Strategies to Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is extending the comment period for the notice of availability that appeared in the *Federal Register* of February 14, 2020, entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration; Draft Guidance for Industry." This supplemental draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act comply with the requirements of our regulation entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration." FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of availability published February 14, 2020 (85 FR 8599). Submit either electronic or written comments on the supplemental draft guidance by August 14, 2020.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1398 for "Mitigation Strategies to Protect Food Against Intentional Adulteration: Supplemental Draft

Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-3712, ryan.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 14, 2020 (85 FR 8599), we published a notice announcing the availability of a supplemental draft guidance for industry entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry." This multichapter supplemental draft guidance for industry is intended to help food facilities required to comply, develop, and implement some of the components of a food defense plan, and meet other requirements under 21 CFR part 121.

The Agency has received a request for an extension of the comment period for 120 days. The request conveyed concern that the current comment period does not allow sufficient time to develop a comprehensive response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until August 14, 2020. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: May 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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